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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,280	12/29/2000	D. Scott Wilbur	33700WC005	6495

441 7590 09/26/2002

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WASHINGTON, DC 20036

EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/750,280

Applicant(s)

WILBUR ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 33-97 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 33-97 are pending. The Preliminary Amendment filed 6/22/01, cancelled claims 1-32 and added claims 33-96. The Amendment filed 2/28/02, amended the specification.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 33-74, 88-96 drawn to a single molecule reagent, classified in class 530, subclass 402.
- II. Claims 75, 80, 97, drawn to method of detecting affinity label bound to biomolecule, classified in class 436, subclass 86.
- III. Claims 76, 78, drawn to a method for diagnosing a condition/disease, classified in class 424, subclass 9.1.
- IV. Claims 77, 79, drawn to a method for treating a condition/disease, classified in class 514, subclass 2.
- V. Claims 81-87, drawn to a kit, classified in class 422, subclass 61.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes can be practiced with another product. For example a radioactive compound with an affinity molecule attached can be used to detect biomolecules, diagnose disorders, and treat disorders.

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Inventions V and I, II, III, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a kit and a molecule and a method of using that molecule are unrelated. The purpose of a kit is to provide a carrier for a given substance. The purpose of a compound is to provide a chemical substance and the purpose of its use is to produce a chemical effect via the compound. A compound does not need to be placed in a kit and a method of using the compound does not require a kit. Thus, these inventions are unrelated.

Inventions II and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a method of binding a compound, a method of treating a disease, and a method of diagnosing a disease are unrelated. A method of finding a compound does not treat or diagnosis a disease, just as treating or diagnosing a disease does not find a compound. Furthermore, treating a disease does not diagnosis a disease and diagnosing a disease does not treat a disease. Thus, these inventions are unrelated. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Claims 33-97 are generic to a plurality of disclosed patentably distinct species comprising trifunctional reagents for conjugation to a biomolecule. In particular, the reagents comprise an affinity ligand, a trifunctional cross-linking moiety, a biomolecule reactive moiety, an effector agent, a linker 1, a linker 2, and a linker 3. Possible affinity ligands include natural biotin, norbiotin, homobiotin, oxybiotin, iminobiotin, desthiobiotin, diaminobiotin, biotin sulfoxide, and biotin sulfone. Possible effector agents include Tc-99m, In-111, I-123, Ga-68, F-18, Br-75, B4-76, I-124, Y-90, I-131, Re-186, Re-188, Cu-67, Sm-153, Lu-177, Bi-212, Bi-213, At-211, and the compounds listed on page 14, lines 15-25 of the specification. Possible biomolecule reactive moieties include, N-hydroxysuccinimide esters, sulfo-N-hydroxysuccinimide esters, and the compounds listed on page 15, lines 20-22 of the specification. Possible trifunctional cross-linking moieties include triaminobenzene, tricarboxybenzene, dicarboxyaniline, and diaminobenzoic acid. Possible linker moieties include ethers, thioethers, carboxylates, sulfonates, ammonium groups, trioxadiazine, dioxadiazine, and the compounds listed on page 18, lines 17-21 of the specification. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from the elected group, for examination purposes only, even though this requirement is traversed.

**Note:** Applicant is respectfully requested to elect an affinity ligand, a trifunctional cross-linking moiety, a biomolecule reactive moiety, an effector agent, and linkers, within the elected group above for examination. It is furthermore respectfully requested that, if possible, a chemical structure and name be supplied with the election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Bob Weilacher on 9/12/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

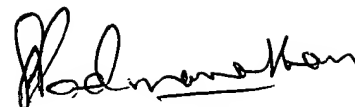
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

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lqw  
September 19, 2002



SREENI PADMANABHAN  
PRIMARY EXAMINER

9/21/02